# ELabELN | Template Use Case White Paper

# Sandwich ELISA Experiment Template

*Structured Documentation for Quantitative Immunoassay — From Plate Coating Through 4PL Standard-Curve Fitting and Unknown Interpolation*

## APPLIES TO

- Academic and life sciences research laboratories
- Biotechnology and protein-analysis R&D groups
- Diagnostics and clinical R&D / biomarker laboratories
- Contract research organizations (CROs)

## RELEVANT COMPLIANCE & INTEGRITY FRAMEWORKS

- FDA 21 CFR Part 11 — Electronic records and signatures
- Good Clinical Practice (GCP) — Clinical biomarker and sample documentation
- EU Annex 11 & GAMP 5 — Computerized systems and software validation
- NIH / NSF reproducibility and data-management requirements

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# 1. Executive Summary

A sandwich ELISA turns a color change in a 96-well plate into a concentration — how much of a cytokine, hormone, or biomarker is present in a sample. That translation depends entirely on two things being right and being recorded: the plate layout (which well held which standard, blank, control, or unknown) and the standard curve (the 4-parameter logistic fit that maps optical density to concentration). Get either wrong, or fail to capture it, and the numbers are meaningless — and worse, they may look perfectly plausible. Because ELISA results are so often compared across plates, across days, and across antibody lots, the reproducibility of the assay lives or dies on whether the plate map, the OD readings, and the curve parameters were captured in a structured, comparable form. Scribbled on a printout, they are not.

The ELabELN Sandwich ELISA Experiment Template solves this by providing a pre-built, fully structured plate record that loads from the template library in a single click. It ships with a 10-step protocol, validated antibody-pair references, pre-wired standard-curve fields, and a full 8×12 plate grid, plus typed inputs for antibody dilutions, sample dilution, standard-curve range, and blank correction. Antibodies, the TMB substrate, and the recombinant standard link to the ELabELN inventory, and the tamper-evident audit trail captures every plate layout, every OD reading, and every curve-fit calculation.

This white paper describes what the template contains, the quantification use case it is designed to support, the upstream and downstream workflows it connects to, the benefits it delivers to the scientist, and how a laboratory can deploy it and begin running assays within days.

> **KEY BENEFIT**
> Labs that adopt the ELISA template stop rebuilding the plate map and standard curve from scratch each run, capture antibody-lot and standard-prep provenance automatically, and gain cross-plate QC — query every plate that used a given antibody lot or standard preparation and compare fit quality side by side — in a record built to support biomarker-validation and 21 CFR Part 11 / GCP review.

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# 2. What Is a Sandwich ELISA, and Why Does Documentation Matter?

## 2.1 The Technique

A sandwich ELISA quantifies a target protein by capturing it between two antibodies. A capture antibody coating the plate binds the analyte; a biotinylated detection antibody binds a second epitope; a Streptavidin-HRP conjugate binds the biotin; and a TMB substrate develops a color whose intensity is proportional to the amount of analyte. Sulfuric acid stops the reaction, and a microplate reader measures optical density at 450 nm. Alongside the unknown samples, a dilution series of a recombinant standard is run to build a standard curve — a 4-parameter logistic (4PL) fit of OD against known concentration — from which the concentration of each unknown is interpolated.

This is the workhorse method for protein-level quantification of secreted analytes: cytokines such as IL-6, hormones, and clinical biomarkers. Its precision is also its fragility. The result for every unknown depends on the standard curve fit on the same plate, on the plate layout being recorded exactly, and on the antibody pair and standard being the expected lots. A shifted curve, a mislabeled column, or an unrecorded antibody-lot change turns a quantitative result into a guess.

Because ELISA numbers are routinely compared across plates and runs, **the plate layout, the OD readings, and the curve parameters — with the reagent lots behind them — are what make one plate's results comparable to another's, which is exactly why they must be captured as structured data rather than a printout.**

## 2.2 The Documentation Problem

Recording ELISAs on a plate-reader printout or an ad-hoc spreadsheet creates a set of interconnected risks:

- The plate layout is redrawn by hand each run, so which well held which sample, standard, or control is easy to transcribe wrong and impossible to query later.
- Standard-curve parameters (4PL coefficients, $R^2$) are noted on a printout, so curve quality cannot be compared across plates to catch a drifting assay.
- Antibody-pair and standard lots are not recorded against the plate, so a lot change that shifts the curve cannot be traced.
- OD readings and interpolated concentrations live in separate files, disconnected from the layout and the reagents that produced them.
- There is no timestamped, attributed record of who ran which plate and when — a baseline requirement for biomarker studies and regulated work.
- Prior runs of the same assay cannot be retrieved to compare, so cross-plate and longitudinal consistency is invisible.

These are the gaps that undermine ELISA reproducibility, and they are the gaps this template was designed to close.

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# 3. Template Overview: What Ships with the Template

The ELabELN Sandwich ELISA Experiment Template is a pre-populated experiment record available to all ELabELN subscribers directly from the template library. It ships configured for sandwich ELISA quantification of human IL-6 in serum samples, with a 10-step protocol covering plate coating through 4-parameter logistic curve fitting and unknown-sample interpolation. The default configuration assumes a commercial matched antibody pair (capture and biotinylated detection), a Streptavidin-HRP secondary, TMB substrate development, a sulfuric-acid stop, and $OD_{450}$ measurement on a microplate reader, with a standard curve spanning 3.13 to 200 pg/mL across eight serial 1:2 dilutions. Every section is editable — the configuration is a tested baseline, not a locked format.

## 3.1 Template Sections at a Glance

The template populates the existing ELabELN experiment sections your lab already works in. Your team edits a working baseline instead of rebuilding the plate map and standard curve from scratch every run.

| Section | What it pre-populates |
|---|---|
| Main Text | Assay summary, antibody-pair notes, and the expected concentration range, authored in the TinyMCE rich-text editor and linked to the upstream sample prep. |
| Extra Fields | Eleven structured, typed fields grouped as Sample, Plate Layout, and Standard Curve — analyte, capture-antibody concentration and dilution, detection-antibody concentration, standard-curve high and low, sample dilution factor, and blank-correction method. Typed values make curve parameters and well-by-well OD queryable across plates. |
| Steps | A 10-step workflow checklist covering plate coating through OD read and curve fit. Each tick is timestamped to the audit trail, and the reader run is auto-logged. |
| Compounds | Capture antibody, biotinylated detection antibody, Streptavidin-HRP, TMB substrate, stop solution, and the recombinant standard pre-linked from the compound database, with lot numbers carried in automatically. |
| Links & Resources | Pre-wired to the lab's IL-6 ELISA SOP v1.8, the antibody-pair datasheet, and prior runs of the same assay. |
| Storage & Files | −20 °C antibody and recombinant-standard aliquot storage, plus labelled attachment slots for plate-reader CSV exports and 4PL curve-fit files (CSV + XLSX). |

Main Text
Assay summary, antibody-pair notes, expected concentration range.
Extra Fields
Typed: analyte, antibody dilutions, std range, sample dilution, blank.
Steps
10-step checklist; each tick timestamped, reader run auto-logged.
Compounds
Capture & detection Ab, Strep-HRP, TMB, stop, standard from inventory.
Links & Resources
IL-6 ELISA SOP v1.8, antibody datasheet, prior plate runs.
Storage & Files
−20 °C antibody & standard aliquots; reader CSV + 4PL fit (CSV + XLSX).

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*Figure 1. The six ELabELN experiment sections pre-populated by the sandwich ELISA template.*

## 3.2 The 10-Step Protocol

The workflow checklist is the operational spine of the template. Each step maps to a discrete bench action and writes a timestamped, user-attributed entry to the audit trail when checked off. The reader run is auto-logged, and the final curve-fit and interpolation steps are performed in the lab's analysis tool, with the resulting parameters recorded as typed fields.

| Step | Action | What it captures |
|---|---|---|
| 1 | Coat plate (capture antibody) | Capture-antibody concentration / dilution |
| 2 | Block | Blocking step |
| 3 | Add samples & standards | Sample dilution factor; standard-curve range |
| 4 | Add detection antibody | Detection-antibody concentration |
| 5 | Add Streptavidin-HRP | Conjugate step |
| 6 | TMB develop | Development |
| 7 | Stop (sulfuric acid) | Reaction stop |
| 8 | Read $OD_{450}$ | Plate-reader OD (reader run auto-logged) |
| 9 | Fit standard curve (4PL) | 4PL coefficients, $R^2$ (external tool) |
| 10 | Interpolate & report | Interpolated unknowns; blank correction; e-signature |

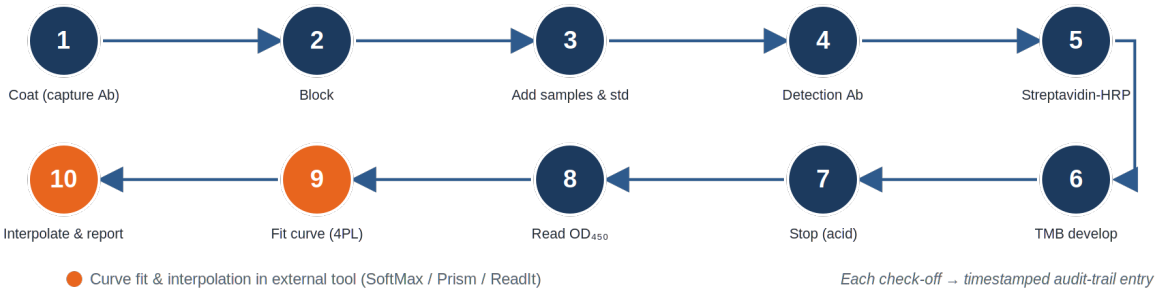


*Figure 2. The 10-step sandwich ELISA workflow — orange steps are the curve fit and interpolation performed in an external analysis tool; every check-off writes a timestamped entry to the ELabELN audit trail.*

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# 4. The Use Case: When and How the Template Is Used

The template is intended as a tested baseline for academic, biotechnology, and diagnostics research labs running protein-level quantification of secreted analytes. It is configured around a recognizable reference — a human IL-6 sandwich ELISA in serum — but the scenarios it serves span the whole quantitative-immunoassay bench.

## 4.1 Cytokine and Biomarker Quantification (Primary Use Case)

The core scenario: measuring the concentration of a secreted protein in a set of samples. The template captures the plate layout, the OD readings, the standard curve, and the interpolated concentrations in one structured record, so a result is fully reconstructable — which well, which standard, which antibody lot — rather than a number on a printout.

## 4.2 Hormones and Other Secreted Proteins

Any secreted analyte with a matched antibody pair fits the same structure. Swap the analyte and antibody pair, adjust the standard-curve range, and the plate layout and curve fields work identically.

## 4.3 Biomarker Validation Studies (GCP)

Biomarker validation and clinical-sample work demand documented, attributable, reproducible assays. The template's audit trail, e-signatures, and structured plate and curve records provide the documentation such studies require, supporting GCP and 21 CFR Part 11 expectations.

## 4.4 Cross-Plate and Longitudinal Studies

Studies that span many plates over weeks or months need results that are comparable plate-to-plate. Because every plate's layout, OD grid, and curve parameters are captured as structured, queryable data, a lab can compare curves and controls across the entire study and detect drift before it corrupts the dataset.

## 4.5 Antibody-Lot and Standard-Preparation QC

Because curve parameters and reagent lots are captured together, the template doubles as a running QC record. A lab can pull every plate that used a specific antibody lot or a specific standard preparation and review fit quality ($R^2$, curve shape, control recovery) side by side — the objective basis for accepting a new lot or investigating a failing one.

## 4.6 Multi-User, Multi-PI, and CRO Settings

Because every ELabELN edition includes unlimited users, the PI, postdocs, students, and visiting collaborators can all run plates from the same template, and the pre-wired SOP enforces one consistent procedure. Granular permissions let the PI decide who may edit ELISA runs versus only review them — the basis a CRO needs to standardize assay documentation across client studies.

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# 5. Dependencies and Connected Workflows

The ELISA template does not exist in isolation. It sits inside a network of connected workflows — upstream, parallel, external, and downstream — that give the plate record its full scientific and provenance value.

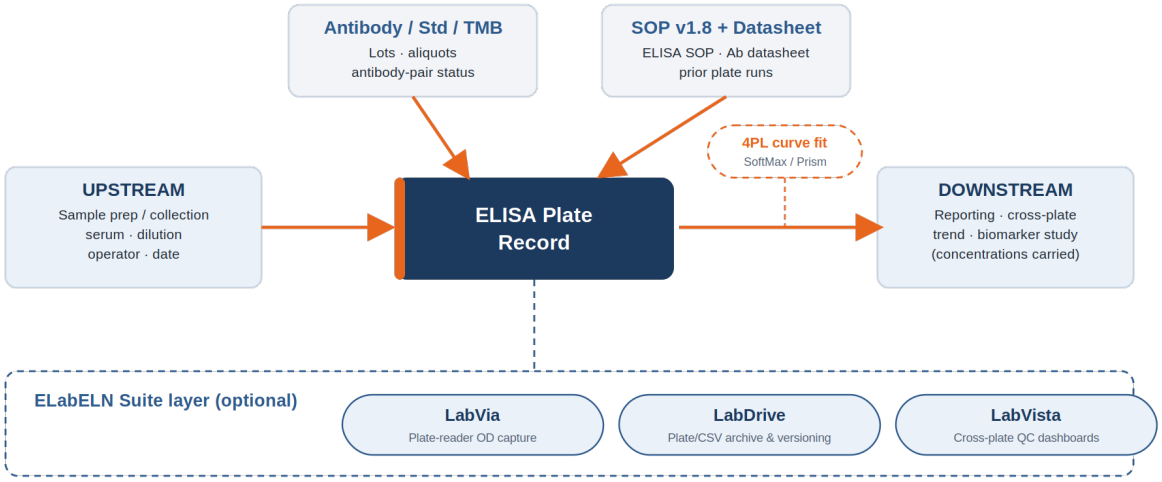


*Figure 3. The template connects an upstream sample prep, parallel inventory and SOP/datasheet systems, an external 4PL curve-fit step, and downstream reporting and cross-plate trend analysis.*

## 5.1 Upstream: Sample Preparation and Collection

Every plate begins with samples — serum, plasma, culture supernatant, or another matrix — collected and diluted for the assay. The template links to the upstream sample-prep record, so opening a plate surfaces the sample source, the dilution applied, and the operator and date, anchoring each interpolated concentration to the material it came from.

## 5.2 Parallel: Antibody, Standard, and Reagent Inventory

The Compounds section links the capture and detection antibodies, Streptavidin-HRP, TMB substrate, stop solution, and the recombinant standard directly to the ELabELN inventory. Because antibody pairs and standard preparations drive the curve, this traceability is decisive. Through the link the record automatically carries:

- **Lot numbers and aliquot tracking** for every antibody and the standard, so a curve shift can be traced to a specific lot.
- **Antibody-pair status, shown inline**, so a mismatched or unvalidated pair is caught before the plate is run.
- **Expiry and stock levels**, with low-stock warnings before a run, so a plate is not started against a depleted or expired reagent.

Barcode and QR scanning can populate these links from the physical vial, keeping lot capture effortless.

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## 5.3 Parallel: SOPs, the Antibody Datasheet, and Prior Runs

The Links section connects the plate to the lab's version-controlled IL-6 ELISA SOP (v1.8 by default), the antibody-pair datasheet, and prior runs of the same assay. The version-controlled SOP records which procedure each plate followed, and the link to prior runs makes cross-plate comparison a starting point rather than a search.

## 5.4 External: The Plate Reader and 4PL Curve Fit

The microplate reader produces the $OD_{450}$ values, and the 4PL curve fitting is performed in the lab's preferred analysis tool — SoftMax Pro, GraphPad Prism, or ReadIt. ELabELN is the system of record around that analysis: the full 8×12 plate grid with OD readings, standard concentrations, sample IDs, and interpolated unknowns lives in the spreadsheet editor, and the fit parameters (4PL coefficients, $R^2$) are recorded as typed fields with the fit file attached. The plate, the evidence, and the result stay together in one record.

## 5.5 Downstream: Reporting and Cross-Plate Trend Analysis

The interpolated concentrations feed reporting and, because they and the curve parameters are typed and queryable, cross-plate and longitudinal trend analysis. A study spanning many plates can be assembled and reviewed for consistency directly from the structured records.

## 5.6 The ELabELN Suite: Instruments and Dashboards

Everything above is available in ELabELN Standard. Labs on the ELabELN Suite gain three layers that connect to the same record: LabVia captures OD data directly from the microplate reader; LabDrive adds metadata search, versioning, and role-based access across plate and CSV archives; and LabVista builds cross-plate QC dashboards on the structured plate and curve metadata. The same audit trail and data-integrity controls span all layers.

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# 6. How the Scientist Benefits

The template is built to deliver value at the bench, not just to the quality system. The benefits compound with every plate a lab runs.

## 6.1 Start From a Tested Baseline, Not a Blank Plate Map

The scaffold — protocol, plate layout, typed fields, antibody and standard links, SOP and datasheet — is already built. The scientist edits a working configuration to match the analyte and antibody pair they actually measure, rather than rebuilding the plate map and standard curve from scratch each run. The first plate is faster, and every subsequent one is consistent with it.

## 6.2 Document by Doing

Checking off each of the 10 steps as it happens produces a contemporaneous, timestamped record as a by-product of the assay, and the reader run is auto-logged. There is no separate write-up to reconstruct later.

## 6.3 Never Lose Antibody-Lot or Standard Provenance Again

Because the antibodies, Streptavidin-HRP, TMB, and recombinant standard are linked to inventory, their lot numbers are captured automatically and permanently on every plate. When a curve shifts, the reagent-lot history is on the record — closing the most common ELISA troubleshooting gap by default.

## 6.4 Cross-Plate QC You Can Query

Typed plate layout, OD, and curve-parameter fields make QC queryable. A scientist can pull every plate that used an antibody lot or standard prep, compare $R^2$ and control recovery at a glance, and catch a drifting assay early — instead of discovering an inconsistency after a study is complete.

## 6.5 Produce Audit-Ready Records for Biomarker and Regulated Work

The tamper-evident audit trail, version-controlled SOP linkage, and electronic signatures mean the record that results from normal use is already structured to support cross-plate reproducibility documentation, biomarker-validation studies, and FDA 21 CFR Part 11 and GCP review when the lab's quality system requires it.

> **AT THE BENCH, IN PRACTICE**
> A researcher opens the template, sets the analyte and antibody pair to match today's run, scans the antibody and standard vials to capture their lots, and checks off each step as the assay proceeds. The plate-reader OD values populate the 8×12 grid; the 4PL fit is run in Prism and its coefficients and $R^2$ go into typed fields with the fit file attached. Weeks later, comparing plates across a study, the PI queries every plate that used that antibody lot and sees the curves line up — or spots the one that drifted.

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# 7. The Plate, the Standard Curve, and Cross-Plate QC

## 7.1 The Default Reference: Human IL-6 in Serum

The template ships configured to quantify human IL-6 in serum with a matched antibody pair, a standard curve spanning 3.13 to 200 pg/mL across eight serial 1:2 dilutions, and $OD_{450}$ detection. The default plate layout uses columns 1–2 for the standard curve, column 3 for blanks, columns 4–11 for unknown samples in technical duplicate, and column 12 for a high control — a recognizable arrangement that demonstrates the full plate-and-curve workflow out of the box. Swap the analyte, antibody pair, standard range, or layout to match what your lab runs; the plate-layout field is freeform, so any configuration is supported.

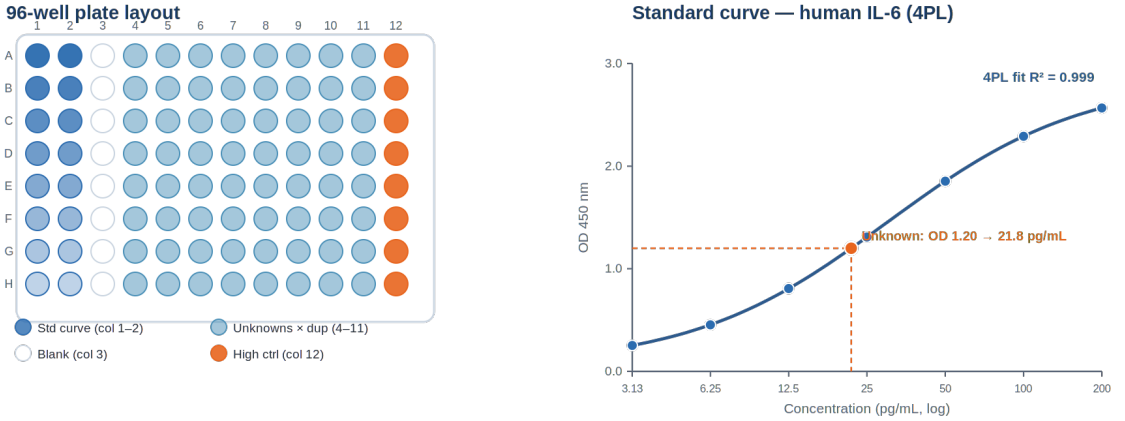


*Figure 4. The default 96-well plate layout and a 4PL standard curve mapping $OD_{450}$ to concentration, with an unknown interpolated from its OD. Illustrative; the plate grid and OD are captured in ELabELN, and the 4PL fit is performed in an external tool with its parameters recorded as typed fields.*

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## 7.2 How the Template Handles the Plate Grid and Curve Parameters

The spreadsheet editor captures the full 8×12 plate in a single structured grid — OD readings, standard concentrations, sample IDs, and interpolated concentrations together. Curve fitting itself is performed in the lab's analysis tool (SoftMax Pro, GraphPad Prism, or ReadIt), and the fit parameters (4PL coefficients, $R^2$) are recorded as typed fields, with the reader CSV and fit file attached. Because the layout, the readings, and the parameters are all structured and queryable, cross-plate trend analysis is straightforward: query every plate that used a specific antibody lot or standard preparation and review fit quality side by side, rather than treating each plate as an isolated result.

| Element | Default configuration | Editable to |
|---|---|---|
| Analyte | Human IL-6 (serum) | Any cytokine, hormone, or biomarker |
| Format | Sandwich ELISA (matched pair) | Direct or competitive ELISA |
| Detection | Biotin detection + Strep-HRP, TMB, $OD_{450}$ | Any compatible detection scheme |
| Standard curve | 3.13–200 pg/mL, 8× serial 1:2 | Any range and dilution scheme |
| Plate layout | Std 1–2, blank 3, unknowns 4–11, ctrl 12 | Any freeform layout |

*Figure 5. The template's default configuration — fully editable for any analyte, assay format, standard range, or plate layout.*

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# 8. Configuring the Template for Your Assay

Adapting the template to a different analyte or format is a matter of editing the relevant sections — not rebuilding the structure.

## 8.1 Swap the Analyte and Antibody Pair

Replace the analyte and the capture/detection antibody pair with those for your target. If the antibodies and standard already exist in the ELabELN compound database, simply re-link them; their lot numbers and pair status flow in automatically.

## 8.2 Change the Standard-Curve Range and Dilution Scheme

Edit the standard-curve high and low and the dilution scheme to match your analyte's dynamic range, and set the sample dilution factor so unknowns fall on the linear portion of the curve.

## 8.3 Move to Direct or Competitive ELISA, and Adjust the Plate Layout

Move from sandwich to direct or competitive ELISA by editing the antibody section, and reshape the freeform plate layout to your run — fewer samples allows more standard-curve replicates; more samples calls for a tighter dilution scheme. Any configuration is supported.

## 8.4 Save a Custom Version

Once configured, save your edits as a private template scoped to your lab, or publish back to the ELabELN template library. Every subsequent run of that assay opens from your configured version, and separate versions can be maintained for different analytes, formats, or regulatory contexts.

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# 9. Getting Started

ELabELN Standard is a cloud-hosted SaaS deployment typically live within one to two business days of account creation. There is no hardware to buy, no IT project, and no per-seat licensing.

1. **Start an ELabELN account.** Visit elabeln.com/get-started. ELabELN Standard runs on LabLynx's managed cloud infrastructure.
2. **Provision your instance.** LabLynx provisions the instance within one to two business days; you receive a URL, admin credentials, and onboarding documentation.
3. **Load the ELISA template.** From the template library, select the sandwich ELISA template and click “Use This Template.” An editable instance opens immediately.
4. **Add your antibodies, standard, and reagents to the inventory.** Enter your antibody pair, Streptavidin-HRP, TMB, stop solution, and recombinant standard with lot numbers and −20 °C aliquot locations. This is a one-time setup step.
5. **Link your SOP and antibody datasheet.** Upload your ELISA SOP and the antibody-pair datasheet, and connect them to the template's Links section.
6. **Customize the template for your analyte.** Edit the analyte, antibody dilutions, standard-curve range, and plate layout, then save as a private team version.
7. **Run your first plate.** Open your saved template, complete the 10-step checklist, enter the plate grid and OD readings, record the 4PL parameters, attach the reader and fit files, and have the PI sign off electronically.

**TYPICAL TIMELINE**

Day 1: Account requested at elabeln.com/get-started. Day 2–3: Instance provisioned; antibody/standard/reagent inventory populated; SOP and datasheet uploaded. Day 3–4: Template configured and saved as a private version for your analyte. Day 4–5: First plate documented in ELabELN with the layout, OD grid, and curve parameters captured and an e-signature.

## 9.1 ELabELN Standard vs. ELabELN Suite

| Capability | Standard | Suite |
|---|---|---|
| ELISA template access | Included | Included |
| Unlimited users | Included | Included |
| Audit trail and e-signatures | Included | Included |
| Antibody / standard / reagent inventory with lot tracking | Included | Included |
| SOP & datasheet linking with version control | Included | Included |
| 8×12 plate grid, reader CSV + 4PL fit attachments | Included | Included |
| LabVia direct plate-reader OD capture | — | Suite layer |
| LabDrive plate/CSV archive search & versioning | — | Suite layer |
| LabVista cross-plate QC dashboards | — | Suite layer |

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# 10. Frequently Asked Questions

### Can I configure the template for my analyte and antibody pair?

Yes. Every section is editable. Swap in a different analyte and antibody pair, change the standard-curve range and dilution scheme, adjust the sample dilution factor, or move from sandwich to direct or competitive ELISA by editing the plate layout and antibody section. Save your edits as a private template scoped to your lab, or publish back to the ELabELN template library.

### Does the template handle standard-curve fitting?

The spreadsheet editor captures the full 8×12 plate with OD readings, standard concentrations, and interpolated unknowns. Curve fitting is performed in the lab's preferred analysis tool (SoftMax Pro, GraphPad Prism, ReadIt), and the fit parameters (4PL coefficients, $R^2$) are recorded as typed fields. The structured record makes cross-plate trend analysis straightforward: query every plate that used a specific antibody lot or standard preparation and review fit quality side by side.

### How does the template handle plate layout for different sample numbers?

The default layout uses columns 1–2 for the standard curve, column 3 for blanks, columns 4–11 for unknowns in technical duplicate, and column 12 for a high control. Edit the layout to match your run — fewer samples means more replicates of the standard curve; more samples means a tighter dilution scheme. The plate-layout field is freeform, so any configuration is supported.

### Is it included in every ELabELN plan?

Yes. Every published template in the ELabELN library is available to all subscribers in both the Standard and Suite editions, with unlimited users in either edition and no per-template fee.

### Can my whole lab use this template?

Yes. Every ELabELN edition includes unlimited users, so the PI, postdocs, grad students, rotating researchers, and visiting collaborators can all use the template without per-seat charges. Granular permissions let the PI control who can edit ELISA runs versus only review them.

### How quickly can my lab start running ELISAs in ELabELN?

ELabELN Standard cloud deployment is typically live in one to two business days. Once the instance is provisioned, the template loads from the library in a single click, with the analyte, antibody pair, and standard-curve parameters editable to match the assay your lab actually runs.

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## 11. Conclusion

The ELabELN Sandwich ELISA Experiment Template is not simply a digital version of a plate-reader printout. It is a structured, audit-ready, searchable record that connects to your antibody and standard inventory, your SOPs and datasheets, the samples the plate measured, your microplate reader and external curve-fit tool, and the reporting and trend analysis the results feed — and, in the Suite edition, cross-plate QC dashboards. It turns a quantitative immunoassay into a record whose plate map, readings, and curve are captured, comparable, and defensible.

For a laboratory that runs ELISAs regularly, the benefit compounds with every plate. Plate layouts, OD readings, and curve parameters accumulate into one queryable, cross-plate QC history. Every antibody lot and standard prep is traceable. Every SOP version is documented. Every plate is timestamped, and every result is authenticated — so a shifted curve or a mislabeled well can no longer quietly undermine a biomarker measurement, and a drifting assay is caught before it costs a study.

The template is available to all ELabELN subscribers today. A new instance is live in one to two business days, and the first structured plate is typically complete within a week of account creation.

**GET STARTED**

Visit elabeln.com/get-started to request your ELabELN instance, or contact LabLynx at 866.522.5969 or info@lablynx.com. Load the sandwich ELISA template, configure it for your analyte and antibody pair, and run your next plate from a tested, audit-ready baseline.

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